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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-14VP]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Community Context Matters Study - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The daily use of specific antiretroviral medications by persons without HIV infection, but at high risk of sexual or injection exposure to HIV, has been shown to be a safe and effective HIV prevention method. The Food and Drug Administration approved the use of Truvada® for preexposure prophylaxis (PrEP) in July 2012 and CDC has issued clinical practice guidelines for its use. With approximately 50,000 new HIV infections each year, increasing rates of infection for young MSM, and continuing severe disparities in HIV infection among African-American men and women, incorporation of PrEP into HIV prevention is important. However, as a new prevention tool in very early stages of introduction and use, there is much we need to learn about how to implement PrEP in a real world setting and the need to develop and validate new measurement tools to capture this information.

CDC is requesting OMB approval to collect data over a 3-year period that will be used to (1) assess the utility of new measures developed or adapted to collect information related to this new intervention (PrEP) and (2) evaluate community contextual factors that may impact the acceptability and successful introduction of a new HIV prevention method. The project will be conducted in communities in each of four cities

where PrEP has recently become available through a local community health center.

Once per year for three years, two surveys will be conducted: (1) a community-based survey to be administered to 40 persons per city approached in public venues in the catchment areas of the PrEP clinics, and (2) a key stakeholder survey to be administered to 10 community HIV leaders nominated by PrEP clinic staff and HIV community-based organizations in the clinic communities. Both surveys will collect data on the demographics of the participants, knowledge of PrEP, misinformation about PrEP, and attitudes about it. The neighborhood survey will also include questions about basic HIV knowledge, attitudes, and beliefs as well as information about sexual and drug use behaviors that are indications for PrEP use. For the stakeholder survey, additional questions will be included about type of organization where they work and organizational experience with PrEP. Surveys will be administered face-to-face by trained, local interviewers.

There are no costs to respondents other than their time. The total annual hours are 91.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response
Neighborhood Survey Street Interview Participant	Neighborhood Interview Recruitment Script and Informed Consent	240	1	5/60
Key Stakeholder Participant	Key Stakeholder Telephone Recruitment Script and Informed consent	60	1	5/60
Street Interview Participant	Survey	160	1	20/60
Key Stakeholder Participant	Survey	40	1	20/60

Leroy Richardson,
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